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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,307	01/28/2004	Fang Hu	SSBC-0001 (121300.00003)	1676

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EXAMINER	
JOYCE, CATHERINE	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,307	HU ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-61 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, as drawn to a method for ablating tumor cells in a subject having at least one tumor site, classified in class 424, subclass 93.1.

II. Claims 29-56, as drawn to a method for ablating tumor cells in a subject having at least a first tumor and a distal tumor, classified in class 424, subclass 93.1.

III. Claims 57-59, as drawn to a method for shrinking a distal-nasopharyngeal carcinoma in a subject having the distal nasopharyngeal and a first nasopharyngeal carcinoma, classified in class 424, subclass 93.1.

IV. Claim 60, as drawn to an isolated nucleic molecule comprising a sequence at least 95% identical to SEQ ID NO:1, classified in class 435, subclass 235.1+.

V. Claims 61, as drawn to an isolated nucleic molecule comprising a sequence at least 95% identical to SEQ ID NO:2, classified in class 435, subclass 235.1+.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of Groups I-III are materially distinct methods that differ at least in objectives, method steps and populations treated. While the searches for the inventions of Groups I-III would be overlapping, they would not be coextensive. Thus,

searching all of the groups together would pose an undue search burden. Inventions IV and V are each related to each of inventions I-III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can practice with another materially distinct product such as a different oncolytic adenovirus.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. The following further election of species are required:

If group I or II is elected, selection of method step sequence from the following list is required: contacting the tumor cells with a lytic agent before applying the in vivo stimulus; applying the in vivo stimulus to the tumor before contacting the tumor cells with a lytic agent; contacting the tumor cells with a lytic agent and applying the in vivo stimulus simultaneously.

If group I or II is elected, selection of a tumor type from the following list is required: a nasopharyngeal carcinomas, a chondrosarcoma, a cancer of the colon, non-small cell lung cancer, breast cancer, prostate cancer, ovarian cancer, malignant hepatoma, carcinoma of the esophagus, small cell lung cancer, cancer of rectum, carcinoma of stomach, carcinoma of ovarium, carcinoma of ascites.

If group I or II is elected, selection of a lytic agent from the following list is required: an oncolytic virus, an oncolytic bacteria.

If an oncolytic virus above is elected, selection of an oncolytic virus type from the following list is required: adenovirus, herpes simplex virus, reovirus, Newcastle virus, poliovirus, measles virus, vesicular stomatitis virus.

If an oncolytic virus above is selected, selection of gene product lacking in tumor cells from the following list is required: p53 gene product; an RB gene product.

If an oncolytic virus above is selected, selection of a viral oncoprotein from the following list is required: p53 binding protein; RB binding protein.

If an adenovirus above is elected, selection of particular sequence from the following list is required: the sequence of SEQ ID NO:1; the sequence of SEQ ID NO:2.

If an oncolytic bacteria above is elected, selection of an oncolytic virus from the following group is required: Salmonella, Bifidobacterium, Shigella, Listeria, Yersinia or Clostridium.

If Group I or II is elected, election of a particular gene from the following list is required: an apoptotic gene, a cytolytic gene, a tumor necrosis factor gene, a negative I-κ-β gene, a caspase gene, a γ-globulin gene, or a hα-1 antitrypsin.

If Group I or II is elected, election of stimulus from the following group is required: local hypothermia; high-frequency electromagnetic pulses; radiofrequency diathermy; microwave diathermy; ultrasound diathermy; systemic hyperthermia; an anoxia, a radiation, an alcohol, a glutamine treatment, infection.

If Group I or II is elected, election of heat shock protein from the following list is required: HSP70; HSP30; HSP60; HSP90; HSP94; HSP96; HSP110.

If Group III is elected, election of an oncolytic adenovirus from the following list is required: SEQ ID NO:1 and SEQ ID NO:2.

If Group III is elected, election of a stimulus from the following list is required: a high frequency electromagnetic pulse, a radiofrequency, a microwave diathermy, an ultrasound diathermy.

If Group III is elected, election of a particular chaperone protein from the following list is required: Hsp 70, Hsp 30, Hsp 60, Hsp 90, Hsp 94, Hsp 96, Hsp 110.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP. 809.02(a).

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 of the other invention.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note

that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Catherine M. Joyce
Examiner
Art Unit 1642